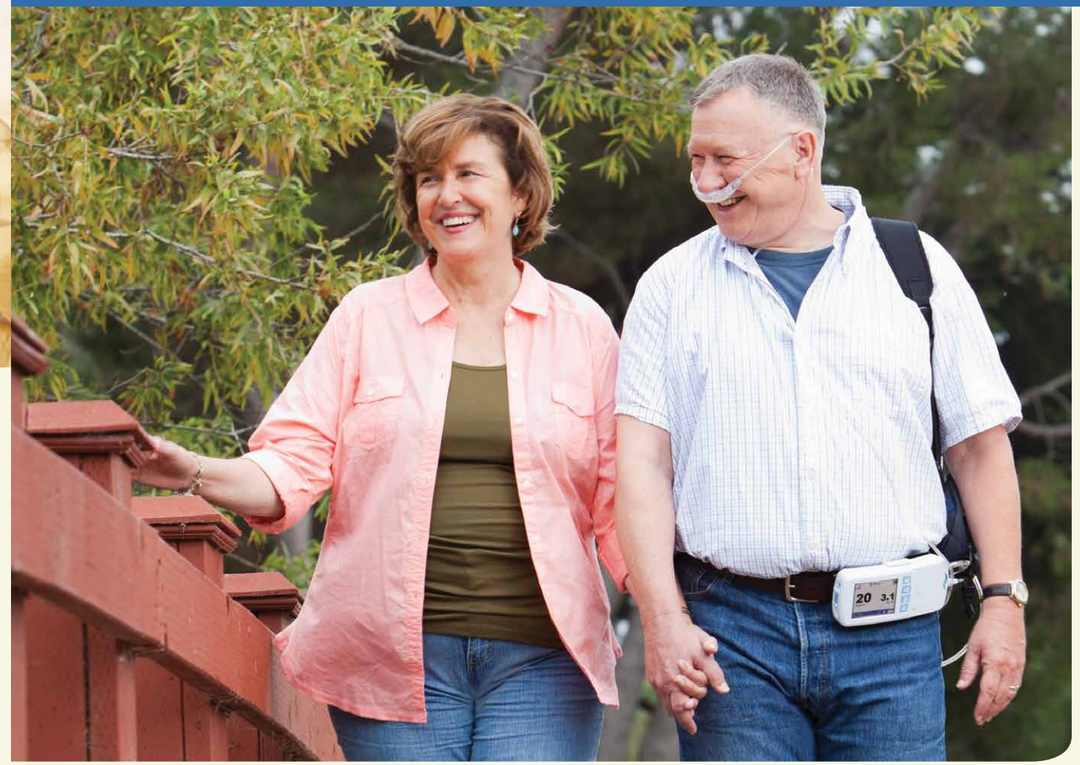

PATIENT Instructions for Use

THE BREATHE NIOV™ VENTILATION SYSTEM

Breathe

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Breathe
NIOV™

PRODUCT WARRANTY

WARRANTY

Breathe Technologies, Inc. warrants that the Breathe Non-Invasive Open Ventilator (NIOV™) is free from defects in material and workmanship for a period of one (1) year from the date of shipment.

Patient interface, accessories and other associated parts are warranted for ninety (90) days from date of shipment.

Breathe Technologies, Inc. will, at its option, either repair, replace, or issue credit for products that prove to be defective during the warranty period.

For warranty service or repair, the product must be returned to Breathe Technologies, Inc. or a service facility designated by Breathe Technologies, Inc. shipping prepaid by the Buyer.

LIMITATION OF WARRANTY

Ordinary maintenance, as specified in this Instructions for Use and the Service Manual, is not covered under the forgoing warranty.

The forgoing warranty does not apply to defects resulting from:

1. Improper or inadequate maintenance of the unit.
2. Improper use or misuse of the unit.
3. Unauthorized modifications or repairs to the unit.
4. Use of the unit with unauthorized accessories, e.g, external battery or AC adapter.
5. Operation of the unit outside the specified environment.

NO IMPLIED WARRANTIES

This warranty is exclusive. There are no other warranties expressed or implied.

LIMITATION OF LIABILITY

Breathe Technologies, Inc. shall not be liable for loss of profits, loss of use, consequential damages, or any other claim based on breach of warranty. Breathe Technologies, Inc.'s liability for damages of any kind shall be limited to the purchase price of the defective unit.

WELCOME

This manual provides detailed information about the Breathe Non-Invasive Open Ventilation (NIOV) System and step-by-step instructions for using its features.

Chapter 1: Introduction includes critical information that must be read before using the system:

Indications for Use outlines who can typically benefit from using the ventilation system.

Safety Information lists precautions that must be taken to ensure safe operation of the ventilation system.

Chapter 2: System Overview gives an overview of the ventilation system's features.

Chapter 3: Using the Ventilation System describes the six basic tasks that you will perform when using the system:

- Check the battery charge.
- Connect and turn on an oxygen supply.
- Connect and wear the Breathe NIOV Pillows Interface.
- Attach the ventilator.
- Turn on the ventilator and choose an activity setting.
- Adjust the trigger sensitivity.

Chapter 4: Alarms and Troubleshooting describes how alarms are displayed and gives information on what triggers them and how to clear them.

Chapter 5: Setup and Care describes procedures for defining ventilator system settings and for caring for the system.

Chapter 6: Icons provides a reference chart for the symbols used.

Symbols and Conventions

To make it easier to find information you need and alert you to potential hazards, the following symbols and conventions are used throughout this manual:

This	Means this
	WARNING: Indicates hazards that, if not avoided, may cause severe injury or death.
	CAUTION: Indicates hazards that, if not avoided, may result in minor or moderate injury, or damage to or impaired performance of equipment.
	TIP: Indicates tips or additional information that may be helpful when using the ventilation system.

The names of menu items and buttons displayed on the ventilator touch screen are indicated with **bold** text. For example, the **Menu** screen has several buttons, including **Home Screen**, **Settings**, and **Information**.

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This document corresponds to the version/revision level effective at the time of delivery. Revisions to documentation are not automatically distributed. Please contact Breathe Technologies to order current revisions.

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CAUTION: Federal law (USA) restricts this device to sale by or on the order of a physician.

The Breathe NIOV Ventilator contains electrical components that must be disposed of according to the guidelines of the WEEE Directive (Waste in Electrical and Electronic Equipment), Directive 2002/96/EC. Follow local regulations when disposing the ventilator.

Breathe NIOV Ventilation System
Patient Instructions for Use
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Technical Support and Customer Service

United States: 1-877-698-1326

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CHAPTER 1

INTRODUCTION

This section includes the critical information that must be read before using the system.

Indications for Use
Clinical Considerations for Use
Patient Participation
Safety Information

INDICATIONS FOR USE

The NIOV Ventilator, with accessories, is a volume assist ventilator intended to aid adult patients with respiratory insufficiency. It is designed for patients that are capable of spontaneously breathing a minimum tidal volume of 3.5 ml/kg of predicted body weight. The device is designed for continuous applications such as patient ambulation, physical therapy, occupational therapy, respiratory therapy, and other rehabilitation efforts in an institutional or home care environment. The device is intended for operation by trained personnel, patients or their caregivers under the direction of a physician.

PATIENT PARTICIPATION

The use of the NIOV Ventilation System requires moderate patient participation, and therefore the patient must be able to understand and comply with instructions.

WARNING: *Use the NIOV Ventilation System only for patients who meet the indications for use. If the ventilation system is used for patients that do not meet the ventilation system indications for use, patients may not receive appropriate respiratory therapy.*

1 INTRODUCTION

SAFETY INFORMATION

Before using the NIOV Ventilation System, you must be appropriately trained and must fully understand potential safety hazards. Read the following safety warnings and cautions in their entirety before using the ventilation system. Additional warnings and cautions can be found throughout this manual.

WARNING: *The NIOV Ventilation System is not designed for patients who cannot spontaneously breathe or who are fully dependent on mechanical ventilation.*

Failure to read the manual may result in product misuse, which may cause equipment damage or patient mistreatment.

If the NIOV Ventilation System is not functioning correctly, you may not receive appropriate respiratory therapy. Always have an alternate means of oxygen therapy available.

Do not allow smoking near oxygen sources or near the ventilator and do not place oxygen sources or the ventilator near any source of direct heat because flammable materials burn more readily in the presence of oxygen.

If the NIOV Ventilation System is not functioning correctly, use your standard oxygen therapy and contact your health care provider.

CAUTION: *Do not use the NIOV Ventilation System in magnetic resonance imaging (MRI) environments. MRI equipment may cause electronic components in the ventilator to malfunction.*

Do not submerge the ventilator in liquids or pour liquids on it. Liquids may cause components in the ventilator to malfunction.

Do not eat, drink, or chew gum while using the ventilator. Food or liquids that make contact with the ventilator may cause components in the ventilator to malfunction. Eating, drinking, or chewing gum may also increase the risk of choking.

When the ventilator is in use, keep it in a well-ventilated area to prevent it from overheating. The ventilator may overheat and be permanently damaged if it is used in an area that is not well ventilated.

CHAPTER 2

SYSTEM OVERVIEW

This section describes the basic parts and functions of the NIOV Ventilation System.

Ventilation System Components
Breathe Pillows Interface
Ventilator Features
Turning the Ventilator On and Off
Touch Screen Features
Touch Screen Energy-Save Mode

VENTILATION SYSTEM COMPONENTS

The NIOV Ventilation System is an ultra-lightweight, wearable, system designed to improve breathing by providing increased ventilation to adult respiratory patients when they need it. Because of the system's portability, patients have greater mobility and can move about freely and easily.

The NIOV Ventilation System consists of the ventilator, Breathe Pillows Interface, oxygen hose, battery charger, purge tube, and belt clip. The ventilation system is intended for use by patients in the home or institutional setting.

Note: The ventilation system does not include an oxygen cylinder. Shipping configurations may vary based on order.

TIP: *The ventilator is shipped in a specially designed, protective box. Do not throw away the box. Keep it for future transportation needs.*

1. Purge tube
2. Oxygen cylinder (not included)
3. Oxygen regulator
4. Oxygen supply hose
5. Ventilator
6. Belt clip
7. Pillows Interface (shipped separately)
8. Battery charger

BREATHE PILLOWS INTERFACE

The Breathe Pillows Interface for use with the ventilator is not included with the ventilation system components and is shipped separately. For instructions on how to fit, adjust, and connect the interface, see the section **Using the NIOV Ventilation System** in this manual and refer to the Breathe Pillows Interface Quick Start guide included with each interface.

WARNING: *Use the NIOV Ventilation System only with the Pillows Interface. If the ventilation system is used with another manufacturer's interface, the ventilator may not function correctly and you may not receive appropriate respiratory therapy.*

CAUTION: *Use a Pillows Interface for a maximum of 30 days. If an interface is used for more than 30 days, its performance may degrade and you may not receive adequate respiratory therapy.*

Do not use a Pillows Interface that is cracked, odorous, broken, or kinked. If a damaged interface is used, you may not receive adequate respiratory therapy.

VENTILATOR FEATURES

The following illustrations identify the ventilator buttons and connections.

1. Touch screen
2. **Activity** buttons
3. **Power** button
4. Power light
5. Speaker
6. Backup alarm buzzer
7. Breath indicator light

Activity and Power Buttons	
	Low Activity button
	Medium Activity button
	High Activity button
	Power button

WARNING: *Do not cover the ventilator speaker or backup alarm buzzer with tape or any other object. Covering the ventilator speaker or buzzer may make it difficult for a patient to hear alarms, which may result in inadequate respiratory therapy.*

Top End of Ventilator

1 Battery charger connection

2 **Alarm Silence** button

3 Not used

Bottom End of Ventilator

1 Interface port

2 Oxygen supply connection

TURNING THE VENTILATOR ON AND OFF

1 **Power** button

- To turn the ventilator on, press the **Power** button.
- To turn the ventilator off, press the **Power** button for approximately three seconds.

Turn On Sequence

When you turn on the ventilator, the green power light is illuminated. The ventilator performs a self test. During the test, all indicator lights should briefly flash and an audible alarm should briefly sound. This self test can take up to 15 seconds to complete. If you do not hear an audible alarm when you turn on the ventilator, contact your health care provider.

1 Green power light is on.

2 Test screen is displayed. (The software version in this screen is for illustration purposes only.)

3 **Home** screen is displayed without data.

4 When the **Home** screen is displayed, the touch screen is ready to use.

TOUCH SCREEN FEATURES

The NIOV Ventilation System uses a touch screen for setting up the ventilator, monitoring patient data, and displaying alarm information. To use the touch screen, simply touch a screen button or an area of the screen you want to make active. An audible "click" indicates the feature you touch is activated.

There are two main ventilator screens: the **Home** screen and the **Menu** screen.

Home Screen

When you turn on the ventilator, after it completes a self test, the touch screen displays the **Home** screen. After the oxygen supply is connected and the patient is wearing the Pillows Interface, when you press a ventilator **Activity** button, the **Home** screen displays patient oxygen flow rate and breath rate.

The following illustration shows the buttons, icons, and information displayed on the **Home** screen.

1 Touch the **Wrench** button to go to the **Menu** screen.

2 Current **Activity** icon and augmentation volume.

3 Touch the **Flip** button to flip the screen 180°.

4 Current breaths per minute (BPM).

5 Average oxygen flow in liters per minute, based on activity setting and patient's current breath rate.

6 **Battery Charge** icon.

7 Current **Activity** icon. Use the ventilator **Activity** buttons to change an activity setting.

8 **Vibration** icon indicating ventilator is in vibration mode.

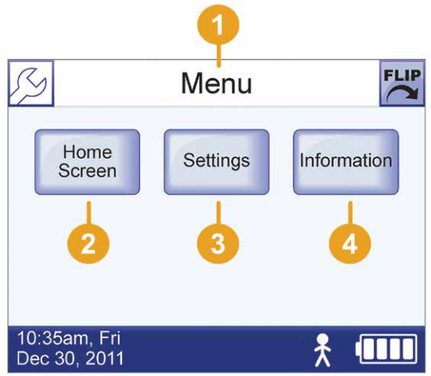
9 Time and date display.

Note: The **Wrench** and **Flip** buttons at the top of the screen and the time and date, current **Activity** icon, and **Battery Charge** icon at the bottom are displayed on all screens.

Menu Screen

Use the **Menu** screen to go to the **Settings** menu, get information about the software version of the ventilator and ventilator use, or go back to the **Home** screen.

To get to the **Menu** screen, on any ventilator screen, touch the **Wrench** button.



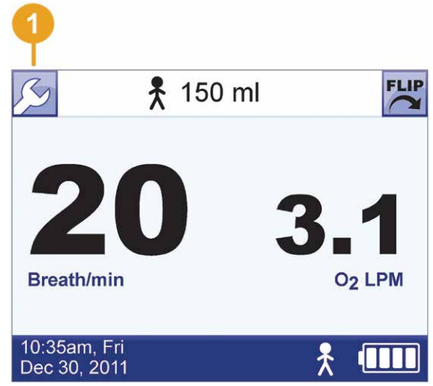
1 Screen title.

2 Touch to go to the **Home** screen.

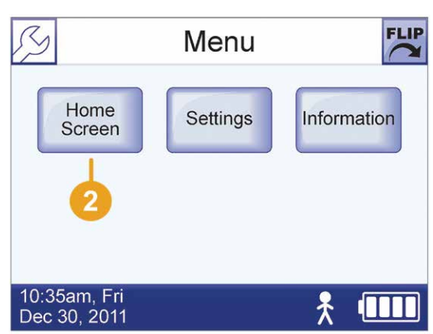
3 Touch to go to the **Settings** screen for **Trigger Sensitivity**, and **Utilities**.

4 Touch to go to the **Software Version** screen for software version and total use time.

Moving Between the Home Screen and Menu Screen



1 Touch the **Wrench** button to go to the **Menu** screen.



2 Touch the **Home** Screen button to go to the **Home** screen.

TOUCH SCREEN ENERGY-SAVE MODE

After two minutes with no user interaction, the touch screen automatically enters energy-save mode and dims the screen. Touching the screen again will reactivate it and display the **Home** screen.

CHAPTER 3

USING THE VENTILATION SYSTEM

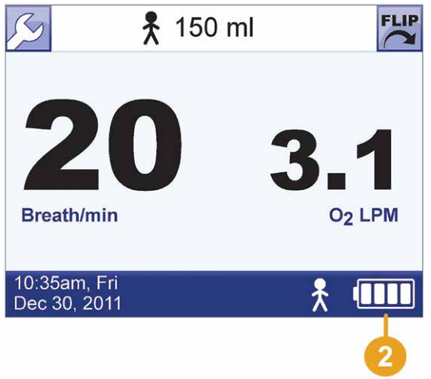
This section describes the six basic steps you need to perform to set up and use the NIOV Ventilation System.

Step 1. Check the Battery Charge
Step 2. Connect and Turn on an Oxygen Supply
Step 3. Connect and Wear the Pillows Interface
Step 4. Attach the Ventilator
Step 5. Turn On the Ventilator and Choose an Activity Setting
Step 6. Adjust the Trigger Sensitivity

STEP 1: CHECK THE BATTERY CHARGE

Before you use the ventilator, check that the battery is fully charged.

1 Press the **Power** button to turn on the ventilator.



2 Check that the fully charged **Battery Charge** icon is displayed before using the ventilation system.

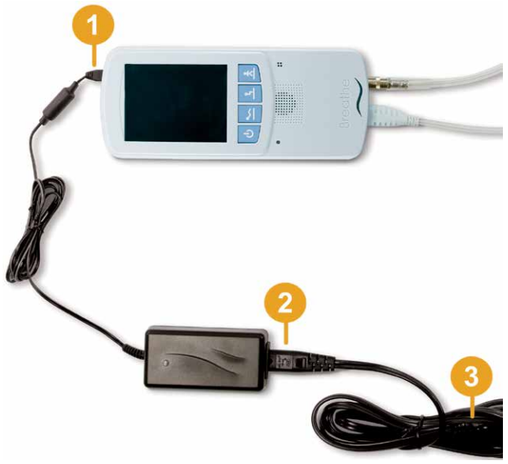
It takes approximately three hours to fully recharge the battery when the ventilator's power is turned off,. A fully charged battery should last approximately four hours.

The **Battery Charge** icon appears on every touch screen.

This icon	Means this
	Charging
	~Fully charged
	~¾ charged
	~½ charged
	~¼ charged
	Less than 1/6
	Empty battery, no charge, or status unknown

Assemble the Battery Charger and Charge the Battery

If the ventilator is off, the battery charger light turns green when the battery is fully charged. The ventilator can be on and in use while the battery is charging, but the battery charger light will remain red. Although the ventilator can be charged while in use, it is recommended that the ventilator is charged with the power off to ensure a full charge. Check the Battery Charge icon on the touch screen to see the current battery charge level.



1 Connect the battery charger cord to the ventilator charger port. The word **UP** on the battery charger cord will be facing the front of the ventilator.

2 Plug the power cord of the battery charger assembly into the battery charger.

3 Plug in the wall plug.

Note: the ventilator can be used while the battery is charging.

CAUTION: *Do not place the battery charger on wet surfaces or use in wet environments. Wet environments may damage the battery charger and may cause electric shock.*

CAUTION: *Use only the Breathe Technologies approved battery charger and cord set with the ventilator. If an unauthorized battery charger or cord set is used with the ventilator, the ventilator may be damaged.*

STEP 2: CONNECT AND TURN ON AN OXYGEN SUPPLY

This section gives instructions on connecting the oxygen regulator and ventilator to an oxygen cylinder, turning the oxygen supply on and off, and replacing an oxygen cylinder.

WARNING: *If the NIOV Ventilation System is not used with a regulator capable of 41–87 psig (nominal 50 psig) with greater than 28 LPM capability, you may not receive appropriate respiratory therapy.*

CAUTION: *Use only a Breathe Technologies approved O_2 supply hose with the ventilator. If an unauthorized O_2 supply hose is used with the ventilator, the ventilator may be damaged.*

TIP: *Use a regulator to regulate the pressure to 41–87 psig (50 psig nominal) before attaching oxygen to the ventilator. Refer to the regulator and oxygen supply manufacturers' instructions.*

TIP: *The oxygen supply hose should remain connected to the ventilator at all times, except when required to be disconnected for maintenance, testing, or replacement. If it is disconnected while the ventilator is on and a therapy level active, an alarm occurs. If this happens, turn the ventilator off, and reconnect the hose.*

Connecting the Regulator to an Oxygen Cylinder

1 Slide the regulator over the neck of the cylinder, and line up the pins on the regulator with the holes in the cylinder neck.

2 Tighten the tee screw on the regulator by turning the handle clockwise.

3 Ensure the barbed outlet airflow gauge is set to 0.

Connecting the Ventilator to an Oxygen Cylinder

1 Turn the ventilator off by firmly pressing the **Power** button for about three seconds.

2 Push the small oxygen supply hose connector onto the oxygen supply connection until it snaps into place.

3 Connect the green oxygen supply hose connector to the oxygen regulator by turning it clockwise.

4 With the ventilator power off and the oxygen supply hose connected to the ventilator and oxygen supply, follow the regulator and oxygen supply manufacturers' instructions for turning on the oxygen supply.

Replacing an Oxygen Cylinder

When an oxygen cylinder needs to be replaced:

1 Turn the ventilator off by firmly pressing the **Power** button for at least three seconds.

2 Follow the oxygen and regulator manufacturers' instructions for shutting off the oxygen supply.

3 Disconnect the ventilator oxygen supply hose from the oxygen supply.

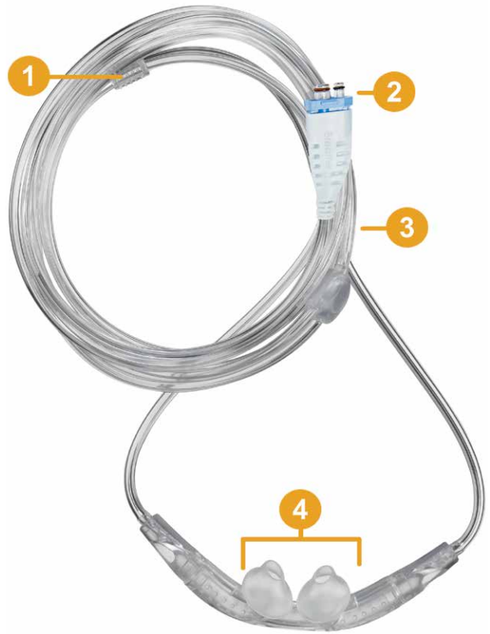
4 Connect the ventilator oxygen supply hose to a new oxygen cylinder.

5 Follow the oxygen and regulator manufacturers' instructions for turning on the oxygen cylinder.

STEP 3: CONNECT AND WEAR THE PILLOWS INTERFACE

Before using the Pillows Interface, visually inspect it for damage.

The interface comes in four sizes: extra small, small, medium, and large. Your health care provider determines what size is best for you. The interface assembly is packaged clean but not sterile.



1 Tube fit adjustor

2 Ventilator connector

3 Interface tubing

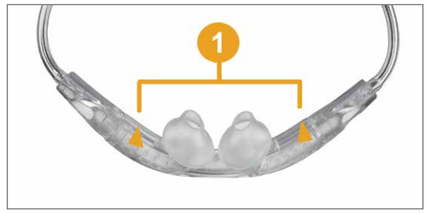
4 Interface pillows

Connecting the Interface to the Ventilator

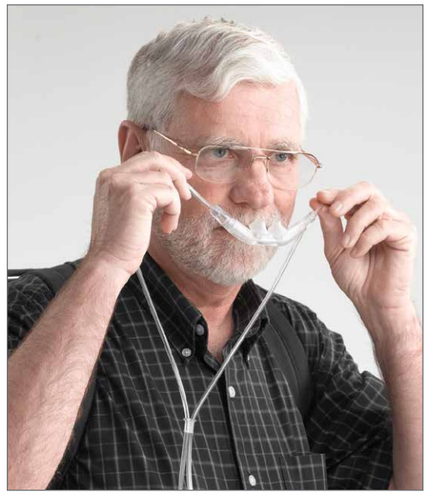
1 Turn off the ventilator.

2 Plug the interface into the ventilator port.

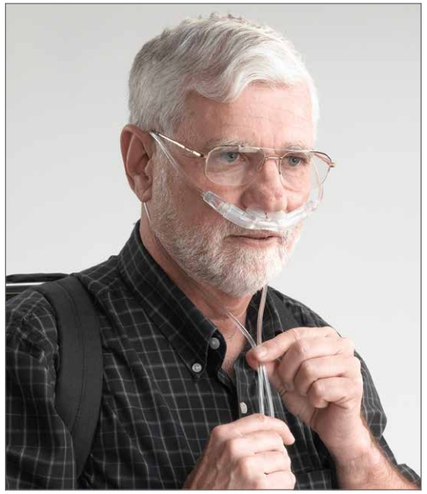
Wearing the Interface



1 Place the interface in front of you with the arrows underneath pointing up and the curve of the interface towards you.



2 Loop the interface tubing over the ears so the pillows of the interface are positioned snugly inside the nostrils. For proper positioning of the interface, see the next section in this Step: **Checking the Interface Positioning**.



3 Adjust the tubing length under the chin so that the interface is comfortably secured.

Checking the Interface Positioning

The interface is placed correctly if the following conditions are met:

- The interface pillows rest snugly inside the nostrils, as shown.

- The fit is comfortable.
- The interface does not make breathing difficult.
- Air does not flow to the eyes, cheeks, or lips.

If any one of these conditions is not met, reposition the interface. If problems persist, contact your health care provider.

TIP: *When the interface is in use, periodically check that it is positioned correctly and make adjustments as required. If skin becomes irritated, stop using the device, and contact your health care provider.*

STEP 4: ATTACH THE VENTILATOR

You can attach the ventilator to a belt or waistband. Instructions here describe how to use the belt clip to attach the ventilator to a belt or waist band. The ventilator can be worn on either the right or left side.

1 Position the clip over the belt, and push down until it is secure.

2 Line up the belt clip with the ventilator sockets, and push down until the clip audibly snaps into place.

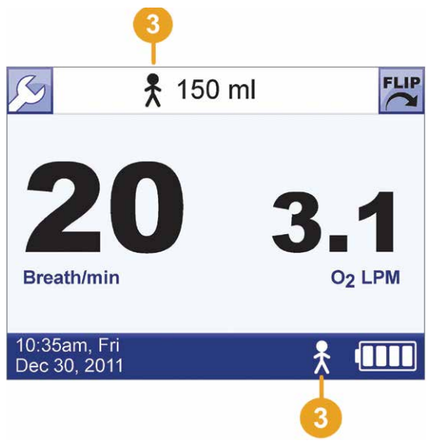
CAUTION: *Make sure the clip is securely fastened to the belt and the ventilator. If the clip is not securely fastened to the belt or the ventilator, the ventilator may drop and be damaged.*

STEP 5: TURN ON THE VENTILATOR AND CHOOSE AN ACTIVITY SETTING

When you first turn on the ventilator, no activity setting is active. The three **Activity** buttons on the ventilator (**Low Activity**, **Medium Activity**, **High Activity**) correspond to three different augmentation volumes prescribed by a physician. Choose an **Activity** button appropriate for your level of activity. You can change the level at any time.

1 Turn on the ventilator.

2 Press an **Activity** button for about one second until you hear a tone that indicates it is active.

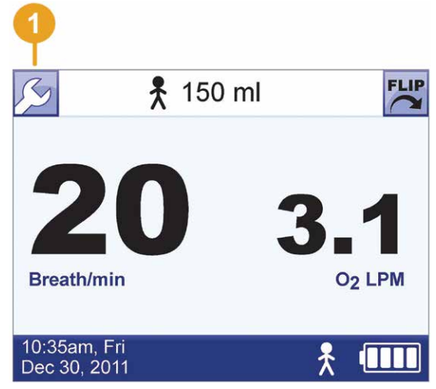


3 Confirm the selected **Activity** icon is displayed on the touch screen (**High Activity** shown).

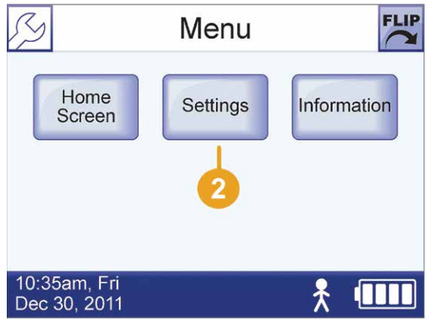
STEP 6: ADJUST THE TRIGGER SENSITIVITY

Trigger sensitivity determines how easily your breath triggers the ventilator to deliver oxygen. For shallow breathing, set the trigger sensitivity to a low number. You can choose a setting between 0 and 9. Zero is the most sensitive and 9 is the least sensitive setting.

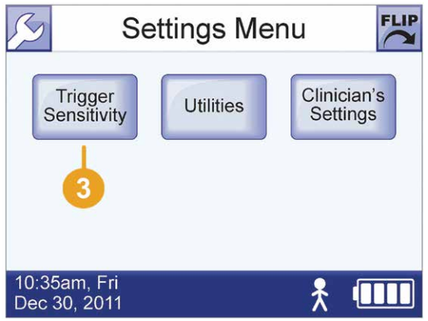
Getting to the Trigger Sensitivity Screen



1 On any ventilator screen, touch the **Wrench** button.

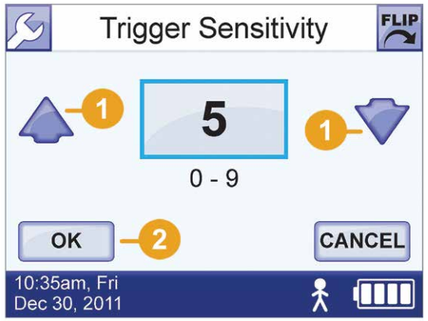


2 On the **Menu** screen, touch **Settings**.



3 On the **Settings Menu** screen, touch **Trigger Sensitivity**.

Changing Trigger Sensitivity



1 On the **Trigger Sensitivity** screen, touch the **Up** arrow to increase the value or the **Down** arrow to decrease it. If you press and hold an arrow, the number automatically increases or decreases.

Note: The lower the number, the more sensitive the setting.

2 When you are finished, touch **OK**.

3 In the message asking if the settings are **OK**, touch **Confirm**.

Note: Changes to settings only take effect when you touch **Confirm**.

CHAPTER 4

ALARMS AND TROUBLESHOOTING

This section describes the alarm functions and possible troubleshooting solutions.

Audio Alarm Sounds
Alarm Message Display
Active Alarms Window
Silencing and Clearing Alarms Summary
NIOV Ventilation System Alarms
Additional Troubleshooting Situations

4 ALARMS AND TROUBLESHOOTING

An alarm indicates a condition that needs to be identified and resolved. There are three alarm priority levels: high, medium, and low. This section describes alarm priority levels, the alarm messages displayed at the top of the touch screen, and the **Active Alarms** window. The section also includes tables that list the possible causes of an alarm and the options for resolving it.

AUDIO ALARM SOUNDS

Each alarm priority level has a distinct sound, described as follows:

Alarm Priority Levels and Corresponding Sounds

Alarm priority: High-priority alarm
Sound: Sequence of two sets of five tones

Alarm priority: Medium-priority alarm
Sound: Sequence of three tones

Alarm priority: Low-priority alarm
Sound: Single tone

ALARM MESSAGE DISPLAY

When an audible alarm occurs, an alarm message flashes at the top of the touch screen. The priority level of an alarm is indicated by the color and the rate at which the message flashes.

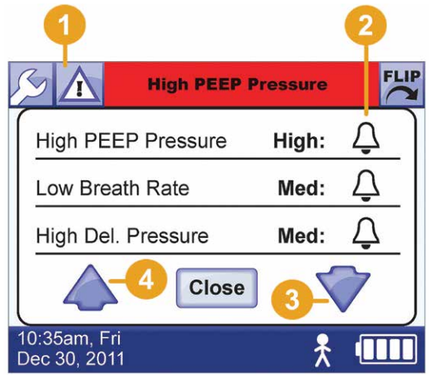
A red, rapidly flashing alarm message is a high-priority alarm and indicates a situation that requires immediate attention.

A yellow, steadily flashing alarm message is a medium-priority alarm and indicates a potentially hazardous situation that must be resolved in a timely manner.

A blue, non-flashing alarm message is a low-priority alarm and indicates a problem that is not hazardous but should be resolved.

ACTIVE ALARMS WINDOW

Multiple alarms may occur at the same time. Touch the **Active Alarms** button at the top of the touch screen to display a list of active alarms.

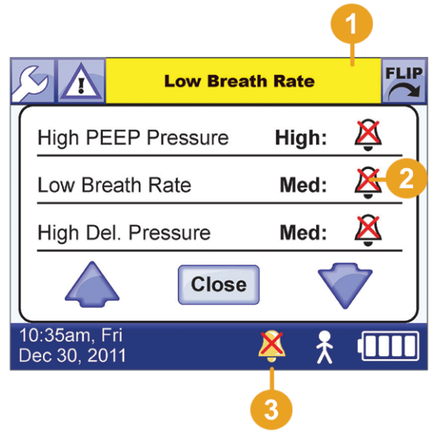


1 Touch the **Active Alarms** button to display the alarm list.

2 **Alarm** icon.

3 **Scroll Down** arrow.

4 **Scroll Up** arrow.



1 Alarm message alternates between each occurring alarm.

2 **Alarm Silenced** icon.

3 **Alarm Silenced** icon is displayed when all alarms are silenced.

TIPS: *The Active Alarms window displays up to three alarms, from highest to lowest priority (red, yellow, blue). If there are more than three alarms, you can use the Scroll Up and Scroll Down arrows to scroll through the list.*

SILENCING AND CLEARING ALARMS SUMMARY

Silencing and clearing alarms is a multi-step process that depends on alarm priority and how many alarms are active.

1 **Silence Alarm** button.

Press the **Silence Alarm** button to temporarily silence the alarm for 60 seconds. Pressing the **Silence Alarm** button silences only one alarm at a time—in audible or vibrating alarm mode. If more than one alarm occurs, press the **Silence Alarm** button once for each alarm. If the alarm is a medium- or high-priority alarm and is not silenced after 60 seconds, the alarm will resume with an additional buzzer.

2 Resolve the condition that triggered the alarm. For help resolving alarms, see the alarm and troubleshooting tables that follow for possible causes of an alarm and options to resolve it. If an alarm silence button is pressed but not resolved, the alarm will sound again after 60 seconds.

3 After resolving a high-priority alarm, touch **OK** in the message that indicates the alarm has been resolved.

Message indicating a high-priority alarm has been resolved.

NIOV VENTILATION SYSTEM ALARMS

The following tables list high-, medium-, and low-priority alarms. For each alarm, the tables list the screen message, the possible causes for the alarm, and the checks and options for resolving it.

High-Priority Alarms

Screen Alert	Cause	Checks and Possible Resolution
High Temperature	CPU or battery temperature is above the allowable limit.	Check to make sure the ventilator is: • Not near a heat source. • In a well ventilated area. • Not covered or enclosed.
High Circuit Pressure	Interface may be pinched or kinked.	Check the interface tube. Replace it if it is pinched or kinked.
High PEEP Pressure	Interface may be blocked.	Inspect and clean the interface per the instruction for cleaning the interface.

Medium-Priority Alarms

Screen Alert	Cause	Checks and Possible Resolution
Breath Timeout	No breath is detected for 20 or 60 seconds, depending on the setting.	• Patient is not breathing or breath is too shallow to trigger augmentation. **Note:** The ventilator is not indicated for patients who are not spontaneously breathing with a minimum volume of 3.5 ml/kg. • Inspect and clean the interface per the instruction for cleaning the interface.

Medium-Priority Alarms

High Breath Rate	Respiratory rate exceeds the set limit.	• Patient is breathing faster than the rate set by a clinician. • Inspect and clean the interface per the instruction for cleaning the interface.
Screen Alert	Cause	Checks and Possible Resolution
High Del. Pressure	Interface pressure during delivery exceeds the maximum expected.	• Check the interface. Replace it if the tubing is torn, bent, or kinked. • Make sure the tubing is not pinched or crushed.
High Gas Pressure	Source gas pressure exceeds the allowable limit.	• Use a regulator to adjust the source gas pressure to within the acceptable range of 41–87 psig (50 psig nominal).
Low Breath Rate	Respiratory rate falls below the set limit.	• Patient's breathing is too shallow to consistently trigger augmentation. • Inspect and clean the interface per the instruction for cleaning the interface. • Patient is breathing through the mouth.
Low Del. Pressure	Interface pressure during delivery fails to exceed the minimum expected.	• Check the interface connection to the ventilator. • Check the interface. Replace it if it is leaking. • Check the oxygen input pressure. If it is <41 psig, use a regulator to adjust it within the acceptable range of 41–87 psig (50 psig nominal). • Check the oxygen supply to ventilator connections.
Low Gas Pressure	Source gas pressure drops below the allowable limit.	• Check the oxygen supply level. • Check the oxygen supply to ventilator connections. • Check the oxygen supply regulator. • Check that the oxygen cylinder valve is fully open.
System Fault	Internal fault detected during operation.	• If a system fault occurs, in the message to reboot the ventilator, touch **OK**. Turn off the ventilator, and turn it on again. • If system fault persists, continue with your prescribed backup therapy and contact your health care provider.

Very Low Battery	Current battery capacity drops below 15%.	• Recharge the battery. • If the battery does not recharge, contact your health care provider.

Low-Priority Alarms

Screen Alert	Cause	Checks and Possible Resolution
Battery Low	Battery capacity drops below 25%.	• Recharge the battery. • If the battery does not recharge, contact your health care provider.
System Fault	System fault detected during power on.	• If a system fault occurs, in the message to reboot the ventilator, touch **OK**. Turn off the ventilator, and turn it on again. • If system fault persists, continue with your prescribed backup therapy and contact your health care provider.

ADDITIONAL TROUBLESHOOTING SITUATIONS

The following table lists situations that may occur during normal use of the ventilation system that do not have an alarm associated with them. The possible causes and options for resolving these situations are also listed.

Additional Troubleshooting Situations

Observation	Cause	Possible Resolution
Breath indicator light is not flashing with the patient's breathing.	• Patient's breath is too shallow to trigger augmentation.	• Change the trigger sensitivity setting to a lower setting.
	• Secretions may have built up on the pillows of the interface, blocking delivery of air.	• Inspect and clean the interface per the instruction for cleaning the interface.
	• Patient is mouth breathing.	• Instruct patient to breathe in through their nose (purse lipped breathing is acceptable).

Additional Troubleshooting Situations

Observation	Cause	Possible Resolution
Breath indicator light is not flashing.	• A ventilator **Activity** button has not been pressed. • Secretions may have built up on the pillows of the interface, blocking delivery of air.	• Press an **Activity** button. • Inspect and clean the interface per the instruction for cleaning the interface.
Buzzer sounds continuously at a constant pitch for two minutes or more.	• The ventilator battery is internally disconnected. • The backup buzzer will sound for two to five minutes before it is silenced.	• Contact your health care provider.
Gas delivery is causing coughing or irritation in airway.	• Interface is not positioned correctly.	• If symptoms persist, stop treatment with the ventilator, and contact your physician.
No volume output.	• Oxygen supply is disconnected. • Oxygen supply is empty. • Ventilator is not on. • Battery is depleted. • Ventilator is inoperative.	• Reconnect the oxygen supply. • Replace the oxygen supply. • Turn the ventilator on. • Recharge the battery. • If there is no volume output, contact your health care provider.
Oxygen supply does not last as long as expected.	• User breath rate is higher than expected. • Oxygen supply is not full at the start of use. • The gas regulator is not properly connected to the oxygen cylinder.	• Obtain a new oxygen supply. • Reconnect the gas regulator to the oxygen cylinder.

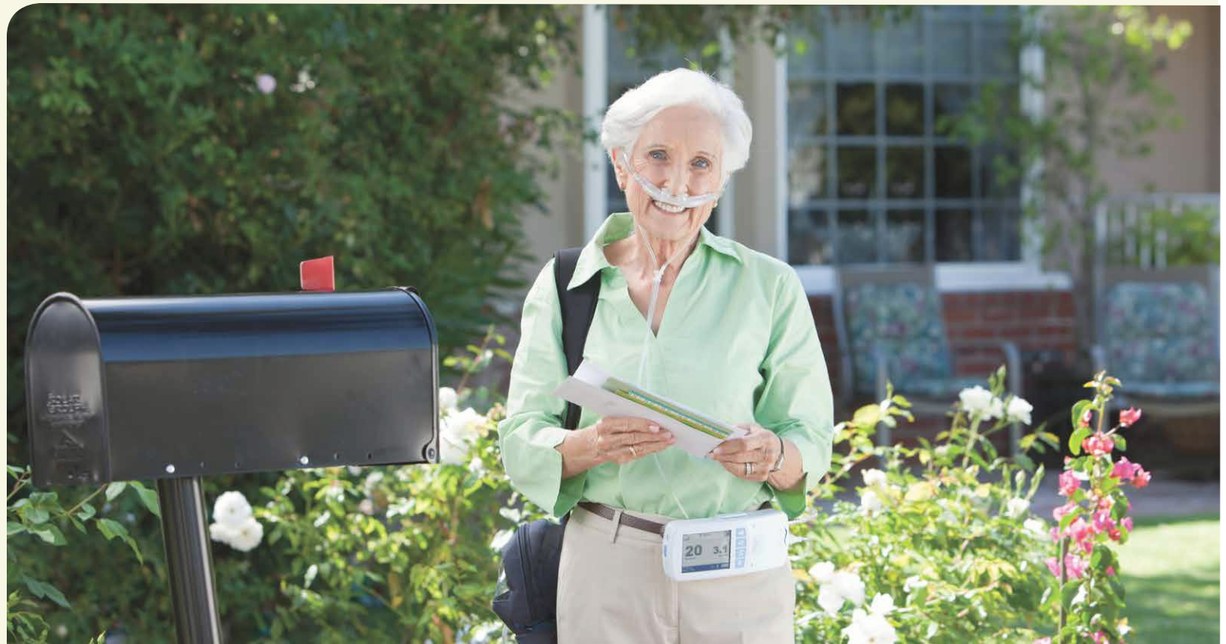
Observation	Cause	Possible Resolution
Ventilator battery does not last as long as expected after a recharge.	• Battery is not charged completely. • Battery life is nearing its end. • Battery has become untrained.	• Recharge battery. • Contact your health care provider. • Retrain the battery, as shown in section 5.
Ventilator is autocycling (delivering gas without being triggered by the patient's breathing or delivering gas multiple times during one breath).	• Secretions have built up on the pillows of the interface. • Ventilator is triggered by movement of the interface. • Ventilator is in breath timeout mode, with timeout augmentation set to 12 BPM.	• Inspect and clean the interface per the instruction for cleaning the interface. • Adjust trigger sensitivity to a higher number.
Ventilator is triggering during exhalation.	• Secretions have built up on the pillows of the interface.	• Inspect and clean the interface per the instruction for cleaning the interface.
Ventilator sometimes misses breaths.	• User is breathing faster than 40 BPM. • Secretions have built up on the pillows of the interface.	• It is normal for the ventilator to limit augmentation to less than 40 BPM. • Inspect and clean the interface per the instruction for cleaning the interface.
Ventilator sounds like it is triggering, but no gas is being delivered.	• No oxygen supply is connected.	• Reconnect oxygen supply.

CHAPTER 5

SETUP AND CARE

This section describes how to change settings using the Utilities menu and instructions on basic care of the system.

Changing Ventilator Settings
Setting Time and Date
Setting Vibration Mode
Setting Audio Loudness
Adjusting Screen Brightness
Viewing Software Version Information
Caring for the NIOV Ventilation System
Battery Retraining and Replacement
Oxygen Supply Information

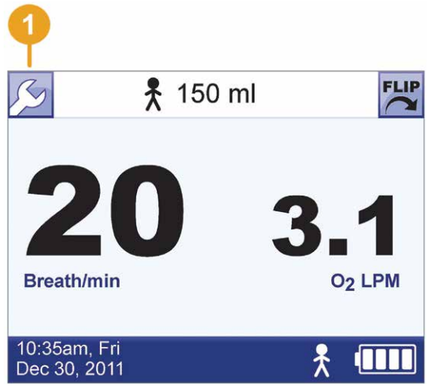


This section describes how to change settings using the **Utilities** menu and display the **Information** screen, which shows the ventilator software version and the total time the ventilator has been in use. This section also gives instructions on basic care of the ventilation system.

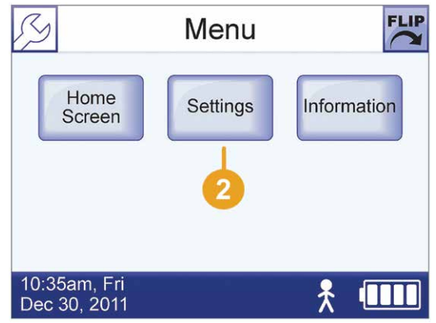
CHANGING VENTILATOR SETTINGS

With the **Utilities** menu, you can change the time and date, brightness of the touch screen, volume of audible alarms, and set alarms to vibrate mode.

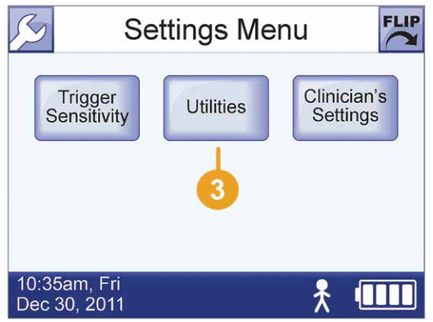
Getting to the Utilities Menu



1 On any ventilator screen, touch the **Wrench** button.

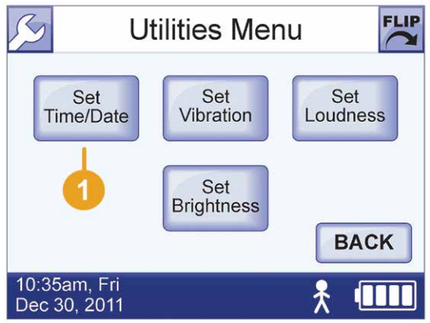


2 On the **Menu** screen, touch **Settings**.

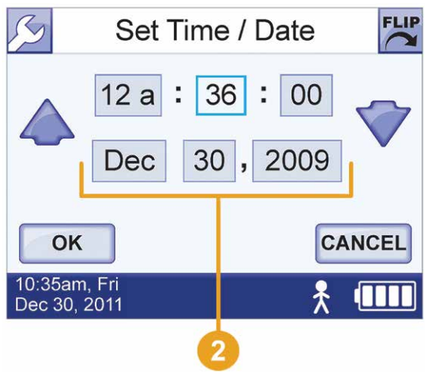


3 On the **Settings Menu** screen, touch **Utilities**. (The **Clinician's Settings** menu is for clinician use only.)

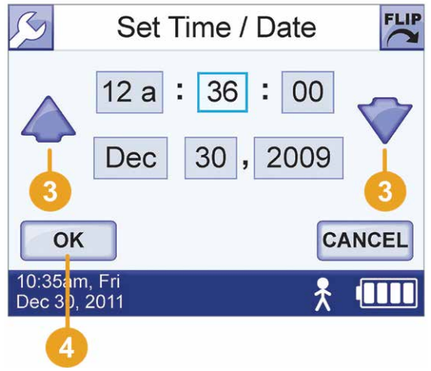
SETTING TIME AND DATE



1 On the **Utilities Menu** screen, touch **Set Time/Date**.



2 On the **Set Time/Date** screen, touch the box you want to change.



3 Touch the **Up** arrow to increase the value in the box or the **Down** arrow to decrease it. If you press and hold an arrow, the value automatically increases or decreases.

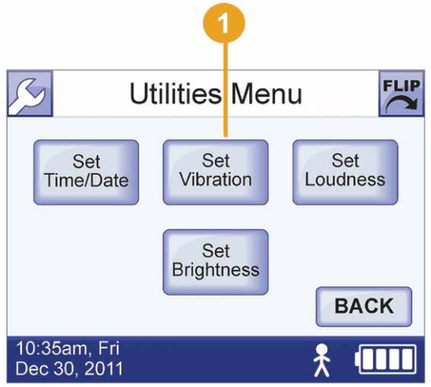
4 Repeat steps **2** and **3** for each box you want to change, and then touch **OK**.

6 In the message asking if the settings are **OK**, touch **Confirm**.

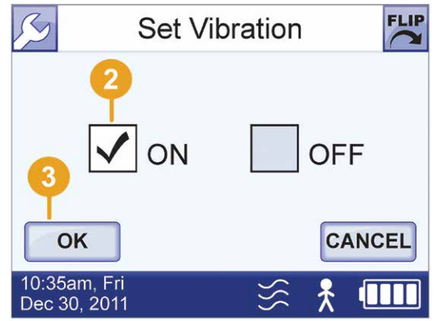
Note: Changes to settings only take effect when you touch **Confirm**.

SETTING VIBRATION MODE

The **Set Vibration** screen lets you change alarms from audible tones to a vibration. However, if a low- or medium-priority vibrating alarm occurs and is not resolved in 60 seconds, an audible alarm occurs. For a high-priority alarm, an audible tone immediately occurs with a vibration alarm with no delay.



1 On the **Utilities Menu** screen, touch **Set Vibration**.



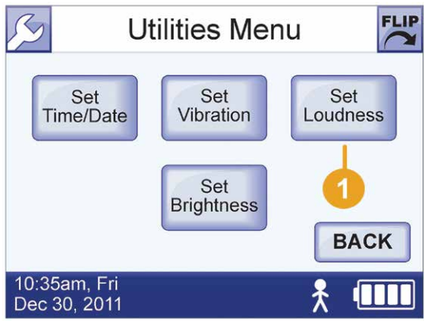
2 On the **Set Vibration screen**, touch **On** or **Off**.

3 When you are finished, touch **OK**.

4 In the message asking if the settings are **OK**, touch **Confirm**, and check that the **Vibrate** icon appears at the bottom of the touch screen, indicating the ventilator is in vibrate mode.

Note: Changes to settings only take effect when you touch **Confirm**.

SETTING AUDIO LOUDNESS



1 On the Utilities Menu screen, touch **Set Loudness**.

2 Touch the **Up** arrow to increase the volume level or the **Down** arrow to decrease it. If you press and hold an arrow, the number automatically increases or decreases.

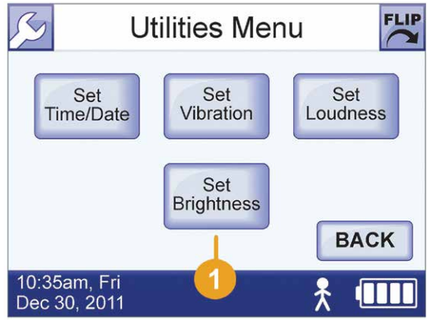
You can choose a loudness level between 1 and 5, with 5 being the loudest and 1 the quietest.

3 When you are finished, touch **OK**.

4 In the message asking if the settings are **OK**, touch **Confirm**.

Note: Changes to settings only take effect when you touch **Confirm**.

ADJUSTING SCREEN BRIGHTNESS



1 On the **Utilities Menu** screen, touch **Set Brightness**.

2 Touch the **Up** arrow to increase the brightness or the **Down** arrow to decrease it. If you press and hold an arrow, the number automatically increases or decreases.

You can choose a brightness level between 1 and 5, with 5 being the brightest and 1 the dimmest.

3 When you are finished, touch **OK**.

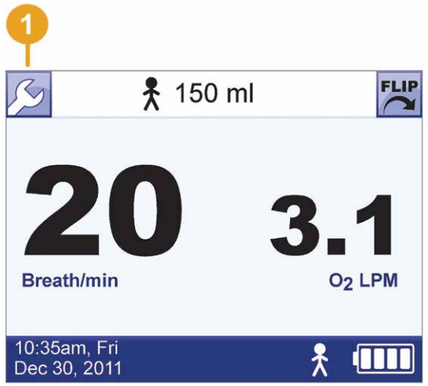
4 In the message asking if the settings are **OK**, touch **Confirm**.

Note: Changes to settings only take effect when you touch **Confirm**.

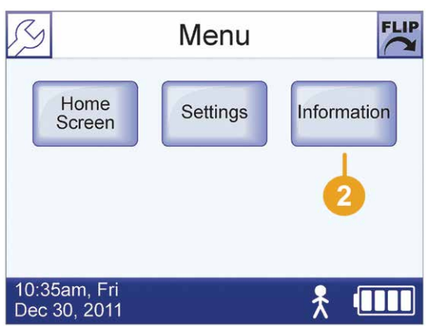
VIEWING SOFTWARE VERSION INFORMATION

The **Software Version** screen displays the software version number, its release date, and the ventilator's total operating time.

Getting to the Software Version Screen



1 On any ventilator screen, touch the **Wrench** button.



2 On the **Menu** screen, touch **Information**.

The screen displays software version, serial number, and total operating time.

CARING FOR THE NIOV VENTILATION SYSTEM

This section gives instructions on how to care for the NIOV Ventilation System, including daily visual checks and guidelines for cleaning and storage.

Daily Visual Checks

Look at the ventilation system components daily. If you uncover any of the following, do not use the ventilation system. Contact your health care provider for instructions on servicing or replacing damaged ventilation system components.

- Check for cracks in the ventilator casing.
- Check the ventilator for loose or damaged buttons, connectors, or other control and alarm components.
- Check the oxygen supply hose and the interface for leaks and loose or damaged cabling or connectors.

Alarm Checks

Confirm that when the ventilator is turned on, it makes audible tones. If tones are not heard, the ventilator should be returned to your health care provider for servicing.

Cleaning the Ventilator

- Wipe the external surfaces of the ventilator with 70% isopropyl alcohol as necessary and between uses.
- Clean the touch screen with a soft microfiber cloth.

CAUTION: *70% isopropyl alcohol may damage the touch screen. When cleaning external surfaces of the ventilator with 70% isopropyl alcohol, avoid contact with the touch screen.*

Cleaning External Surfaces of the Pillows Interface

- If mucus accumulates on the pillows of the interface, use a clean cloth to remove it.
- If dirt is visible on the outside of the interface, use a clean cloth and mild detergent to remove it.

Periodic Cleaning and Purging of the Pillows Interface

Periodically clean the interface following these steps:

1 Disconnect the interface from the ventilator.

2 Submerge the interface end of the interface in a clean container of warm water suitable for drinking, and agitate the interface to clean it.

3 Remove the interface from the water, and hang it so excess water drains from the interface.

4 Before reusing the interface, perform a purge to clear any excess water that may impede air flow. For purging instructions, see the section **Purging the Pillows Interface** that immediately follows.

WARNING: *Do not subject the Pillows Interface to heat sterilization, hot water pasteurization, autoclaving, radiation sterilization, ethylene oxide gas sterilization, or attempt to clean it in a dishwasher or microwave oven. Doing any of these may damage the interface and impair oxygen delivery.*

Purging the Pillows Interface

After cleaning the interface or when you suspect dust or debris has entered the air-flow passage, purge the interface.

Purge tube

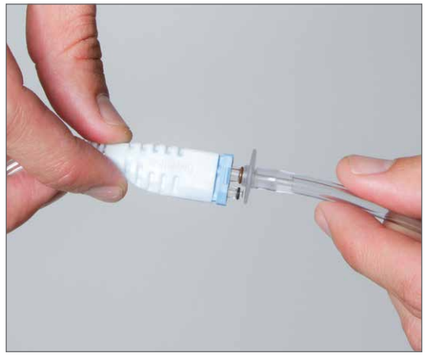
1 Slide the regulator over the neck of the cylinder, and line up the pins on the regulator with the holes in the cylinder neck.

2 Tighten the tee screw on the regulator by turning the handle clockwise.

3 Place the larger end of the purge tube over the barbed outlet.

4 Open the oxygen main valve according to the cylinder and regulator manufacturers' instructions.

5 Rotate the barbed outlet flow regulator to 4 LPM.



6 Firmly press and hold the smaller end of the purge tube over one of the interface ports that connects the interface to the ventilator. Take care not to slide the tube over the O-ring of the port.

Hold the purge tube over the interface port until all the water is purged from the tube.

7 Repeat step 6 for the other interface port.

8 Rotate the barbed outlet flow regulator to the zero or OFF position.

9 Shut off the oxygen main valve according to the cylinder and regulator manufacturers' instructions.

10 Remove the purge tube from the barbed outlet.

Maintenance

The NIOV Ventilation System does not require calibration or routine maintenance. Preventive maintenance, including replacing the O_2 supply hose, is required after 2½ years of use. Contact your health care provider to make arrangements for preventive maintenance.

Environment Specifications

Do not use the NIOV Ventilation System if the ambient temperature is greater than 104°F (40°C) or less than 5°C (41°F).

BATTERY RETRAINING AND REPLACEMENT

Battery Retraining

After a battery has been charged numerous times, the battery charge icon may not accurately display the battery charge.

For example, after fully charging the battery, the battery charge icon may only display 3 bars instead of 4. In this case, the battery has more charge than the battery charge icon indicates. Or, the battery charge icon may display 2 bars when the charge is really only 1. In this case, the battery has less charge than the battery icon indicates. If you notice that the battery seems to last longer or shorter than the battery charge icon suggests, you may need to "retrain" the battery so the icon more accurately displays the battery charge.

Retraining the battery involves discharging it fully and then recharging it fully until the battery icon on the touch screen accurately reflects a full charge and no charge.

To retrain a battery follow these steps:

1. Turn on the ventilator, press an **Activity** button, and let the battery discharge fully until the ventilator shuts itself off.
2. Confirm the ventilator is off. Connect the wall battery charger to the ventilator. Confirm that the charger light is red.
3. Let the ventilator charge until the charger light turns green.
4. Turn the ventilator on. Check that the battery charge icon displays four white bars . If it does not, repeat steps 2 - 4.

Note: You will encounter a **System Fault** alarm after turning on the ventilator once the battery is fully discharged and recharged again. Press **OK** on the alarm display screen to allow the ventilator to reboot.

If after repeating steps 2 - 4 a second time, the ventilator still does not show four white bars, contact your health care provider.

Battery Replacement

The internal ventilator battery is not serviced in the field. It should be replaced every 2.5 years or when runtime degrades to an unacceptable level. Contact your Breathe Technologies service provider to make arrangements for replacing the battery.

OXYGEN SUPPLY INFORMATION

The NIOV ventilator is compatible with compressed medical oxygen cylinders and hospital wall oxygen. The duration of compressed medical oxygen cylinders depends on the volume of the cylinder and the breathing pattern of each patient, which can change throughout the day. Observe your daily oxygen consumption a few times before estimating typical use. The following tables can be used to obtain approximate values only.

Cylinder size B: 164 liters (M-6)

Breaths per minute (BPM)									
	12	**14**	**16**	**18**	**20**	**22**	**24**	**26**	**28**
Tidal volume (ml)	**Duration in hours**								
50	4.7	4.0	3.5	3.1	2.8	2.5	2.3	2.2	2.0
100	2.3	2.0	1.8	1.6	1.4	1.3	1.2	1.1	1.0
150	1.6	1.3	1.2	1.0	0.9	0.8	0.8	0.7	0.7
200	1.2	1.0	0.9	0.8	0.7	0.6	0.6	0.5	0.5
250	0.9	0.8	0.7	0.6	0.6	0.5	0.5	0.4	0.4

Cylinder size D: 425 liters (M-15)

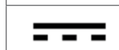
Breaths per minute (BPM)									
	12	**14**	**16**	**18**	**20**	**22**	**24**	**26**	**28**
Tidal volume (ml)	**Duration in hours**								
50	11.8	10.1	8.9	7.9	7.1	6.4	5.9	5.4	5.1
100	5.9	5.1	4.4	3.9	3.5	3.2	3.0	2.7	2.5
150	3.9	3.4	3.0	2.6	2.4	2.1	2.0	1.8	1.7
200	3.0	2.5	2.2	2.0	1.8	1.6	1.5	1.4	1.3
250	2.4	2.0	1.8	1.6	1.4	1.3	1.2	1.1	1.0

Cylinder size E: 660 liters

Breaths per minute (BPM)									
	12	**14**	**16**	**18**	**20**	**22**	**24**	**26**	**28**
Tidal volume (ml)	**Duration in hours**								
50	18.3	15.7	13.8	12.2	11.0	10.0	9.2	8.5	7.9
100	9.2	7.9	6.9	6.1	5.5	5.0	4.6	4.2	3.9
150	6.1	5.2	4.6	4.1	3.7	3.3	3.1	2.8	2.6
200	4.6	3.9	3.4	3.1	2.8	2.5	2.3	2.1	2.0
250	3.7	3.1	2.8	2.4	2.2	2.0	1.8	1.7	1.6

CHAPTER 6 ICONS

Icon	Where used	Meaning
	Ventilator, touch screen	On ventilator, Low Activity button delivers augmentation volume at rate set by clinician in ventilator Clinician's Settings menu. Displayed on the Volume Settings screen as a label for the Low Activity augmentation value set by clinician. Displayed on each ventilator screen if augmentation volume delivery is set to Low Activity.
	Ventilator, touch screen	On ventilator, Medium Activity button delivers augmentation volume at rate set by clinician in ventilator Clinician's Settings menu. Displayed on the Volume Settings screen as a label for the Medium Activity augmentation value set by clinician. Displayed on each ventilator screen if augmentation volume delivery is set to Medium Activity.
	Ventilator, touch screen	On ventilator, High Activity button delivers augmentation volume at rate set by clinician in ventilator Clinician's Settings. Displayed on the Volume Settings screen as a label for the High Activity augmentation value set by clinician. Displayed on each ventilator screen if augmentation volume delivery is set to High Activity.

Icon	Where used	Meaning
	Ventilator	Ventilator power on/off button.
	Ventilator	Indicates communication port. This port is only used by the manufacturer.
	Ventilator	Orientation marker for power-in port.
	Ventilator and Product label	Indicates direct current and denotes the location where the battery charger is plugged into the ventilator.
	Ventilator	On the ventilator, the Alarm Silence button turns off vibrator or audible alarm.
	Touch screen	Displayed in the Active Alarms window of the touch screen if an active alarm has not been silenced.
	Touch screen	Displayed in the Active Alarms window of the touch screen if an active alarm has been silenced. Displayed on the bottom of each ventilator screen if all active alarms have been silenced.
	Touch screen	Displayed on each ventilator screen if battery status is unknown or charge is critically low.
	Touch screen	Displayed on each ventilator screen if battery has approximately 1/6 of its charge remaining.
	Touch screen	Displayed on each ventilator screen if battery has approximately ¼ of its charge remaining.
	Touch screen	Displayed on each ventilator screen if battery has approximately ½ of its charge remaining.

6 ICONS

Icon	Where used	Meaning
	Touch screen	Displayed on each ventilator screen if battery has approximately ¾ of its charge remaining.
	Touch screen	Displayed on each ventilator screen if battery charge is approximately full.
	Touch screen	Displayed on each ventilator screen if battery is charging.
	Touch screen	Displayed on each ventilator screen. Touching the Wrench button displays the Menu screen.
	Touch screen	Displayed on each ventilator screen. Touching the Flip button rotates the touch screen 180°.
	Touch screen	Displayed on each ventilator screen if the ventilator is in vibrate mode.
	Product label	Indicates BF type equipment. Device isolates the patient from any live voltage in the equipment.
IPX1	Product label	Indicates device is protected against dripping water.
	Product label	Indicates a class II device. Device is double insulated and does not require a safety connection to electrical earth (US: ground).
	Product label and documentation	On product indicates accompanying documentation includes important information that must be read before using device.
	Product label	Indicates product emits non-ionizing radiation.

Icon	Where used	Meaning
	Product label	Indicates product is a Bluetooth wireless compatible devise that emits radio frequency waves.
	Product label	Indicates disposal of device must conform to Waste in Electrical and Electronic Equipment Directive 2002/96/EC.
	Product label	Indicates manufacturer and denotes the location of the manufacturer name, address.
	Product label	Indicates date of manufacture.
O2	Product label	Indicates oxygen and denotes the location where the oxygen hose attaches to the ventilator.
	Product label	Indicates catalog number and denotes the location of the part number for the device.
	Product label	Indicates serial number and denotes the location of the serial number for the device.
	Product label	Indicates product meets US standards for use with medical electrical equipment.
	Battery charger label	On battery charger indicates indoor use only and denotes that it should only be used indoors.
	Battery charger label	On battery charger indicates battery charge. The black shaded area represents the amount of charge within the battery (here shown with ~80% charge).
	Battery charger label	On battery charger indicates battery charger meets European economic area standards for use with medical electrical equipment and information technology equipment.

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